54/77

Patents Form 54/77

Patents Act 1977
(Rule 80 and Schedule 4)

Filing a translation in connection with a European patent or a European patent application

(See the notes on the back of this form)

The Patent Office

Cardiff Road
Newport
South Wales
NP10 8QQ

1. Your reference	FW/CT/ETO4858
2. European patent number or publication number of application	EP1074229
3. Full name and address of the or of each applicant for or proprietor of the European patent (UK) Patents ADP number *(if you know it)*	Dr. med. LUIS SCHUSTER Krimhildenstrasse 20, 80639 Munich, GERMANY.
4. What kind of translated document listed at note (c) are you sending with this form? *(Answer by writing 1(i), 1(ii), 1(iii) or 2)*	1[i]
5. Date when the European patent (UK) was granted or amended *(See note (g))*	5 October 2005
6. Full name, address and postcode in the United Kingdom to which all correspondence relating to this form and translation should be sent Patents ADP number *(if you know it)*	POTTS, KERR & CO., 15 Hamilton Square Birkenhead Merseyside CH41 6BR United Kingdom 1313002
7. Do you want the address in part 6 above to be the address for service recorded on the Register or to replace the address for service currently on the Register? *(If so then write 'YES')*	YES
8. Signature / Date	Potts, Kerr & Co. / 3 January 2006
9. Name and daytime telephone number of person to contact in the United Kingdom	F. Wombwell 0151-647-6746

Method of Producing an Endoprosthesis as a Joint Substitute for a Knee Joint

[0001] The invention relates to a method of producing an endoprosthesis as a joint substitute for knee joints and also to an operative set suitable for carrying out operations on knee joints utilising an endoprosthesis which is produced in accordance with such a procedure.

[0002] A surgical intervention on a knee joint is usually taken into consideration by the attending physician when the patient complains about unbearable pain in the knee and disabilities as a consequence of, e.g., rheumatoid arthritis or other joint diseases. The surgical intervention mostly is carried out in a plurality of steps for obtaining an adaption to the single joint parts, that are manufactured industrially and are available in different sizes and shapes. The parts selected for the surgical procedure are fitted finally to sawing surfaces mainly of the femoral condyle, the distal femur, the proximal tibia and the patella. Hereby a vertical alignment to an axis is sought, which is achieved before the surgical intervention e.g., by a X-ray image and by a intramedullary pin align system for the straight alignment connecting the center of the hip, the knee and the malleolus.

[0003] The implantation of such multipart knee joint endoprosthesis is relative laborious. Regarding the frequently relative varying growth of the patient it thereby is disadvantageous, that in such an only approximated restore of the anatomical relations of a healthy knee joint, there occure complications which must be attributed to the mechanics of the implanted components of the endoprosthesis and result e.g., in an anterior knee joint pain syndrome which is caused by an incorrect nonphysiological loading of the femur-patella gliding joint and of the femur-tibia joint.

[0004] For avoiding such complications, which frequently require repeated implantations of a new endoprosthesis with the accompanying disadvantage of a resection of further bone parts there is known already a procedure following patent DE 44 34 539 C2 by which by means of the computer tomography or nuclear spin resonance tomography an image of the damaged knee joint is prepared before the surgical intervention itself. This preoperative image gets subsequently a correction with respect to an approximation to the

contours at least in the femur and the tibia of the damaged knee joint to the contours of a healthy knee joint. After such a correction a virtual postoperative image of the damaged knee joint is prepared which is disposable for a comparison with a preoperative image. From such a comparison a subtraction image is then created which allows to determine from the opposition of the corrected preoperative image and the postoperative image the difference of the contours at least in the femur and the tibia in both of the images. Based on this subtraction image the femoral and tibial component of an endoprosthesis may be manufactured which therefore are tightly adapted individually to the anatomical relations of the damaged knee joint.

[0005] The manufacturing of an endoprosthesis based on a special subtraction image practiced in this procedure needs also because of the implementation of the here by necessary postoperative image additionally to the corrected preoperative image of the referring joint part a higher computer expenditure. Therefore it is possible that a raised number of sources for errors occur by the later conversion of the finally stored data for the substraction images for the three-dimensional manufacturing components of the endoprosthesis.

[0006] The object of the invention is therefore to modify the procedure which works with such tomographic images to manufacture an endoprosthesis, that the attending physician can be provided an operative set for carrying out operations on knee joints in which the therefore needed femoral and tibial components of the endoprosthesis are manufactured without recursing to an comparing image to find out the differences, which were predetermined for the knee joint at a time before and after the operative intervention.

[0007] This task is resolved following the invention by a procedure for producing an endoprosthesis as an joint substitute in knee joints with the characteristics of the claims 1. Further characteristics of the procedure by which the invention is suitable equipped result from the secondary claims which relate to an advantageous application of the procedure to an operative set which results specially suitable for the performance of knee joint operative interventions.

[0008] In accordance with the present invention therefore first a tomographic image of the damaged knee joint is prepared. This image may be obtained by computer tomography

or preferable by nuclear spin resonance tomography, which allows to separate the contours of the joints in a specially sharp manner.

[0009] The tomographic image of the damaged knee joint subsequently is corrected to an approximation to the contours at least of the femoral and the tibial joint parts of the damaged knee joint to the contours in a healthy knee joint. In this therefore virtual correction in a preferable extended position of the knee the posterior and the lower joint surface of the femur and the total tibial joint surface are plotted for a desired achievement of more or less ideal contours in the later implantation of the endoprosthesis during the knee joint surgical intervention itself. The correction hereby may be performed manually in the originally created image or alternatively it is possible to perform the correction by an image of a mirror picture of a healthy knee joint opposite to the damage knee joint. This correction can also be achieved by a comparison with pictures of healthy knee joints that show comparable joint surfaces at least of the femur and the tibia to the damaged knee joint.

[00010] As soon as these corrections are concluded the corrected femoral and tibial joint parts are virtually separated that means segmented. The separation hereby is performed on marked cutting planes which will be followed in the later surgical intervention for the separation performed in the joint bones of the damaged joint parts. This separation will be defined on the femur of the damaged knee joint preferable with three different cutting planes and in the tibia with up to two cutting planes. Therefore visual patterns are obtained which directly are oriented in respect of the damaged knee joint which allow a preparation of the femoral and tibial component congruent to the femoral and tibial joint parts of the femoral and tibial components of an endoprosthesis which is implanted in the later knee joint surgical intervention. The marked cutting planes hereby may be complemented visually with perfect fitting anchoring means in the later severing planes of the joint bone. Such anchoring means may obtain e.g., prominent pegs, which may be fitted snugly into associated peg holes of the resection planes.

[00011] The resection planes marked for the separation of the corrected femoral and tibial joint parts besides that are taken over for the manufacturing of a virtual image of a template separate for the femur and the tibia of the damaged knee joint which will be used as a visual pattern for a three-dimensional implantation aid snugly congruent with a knee joint.

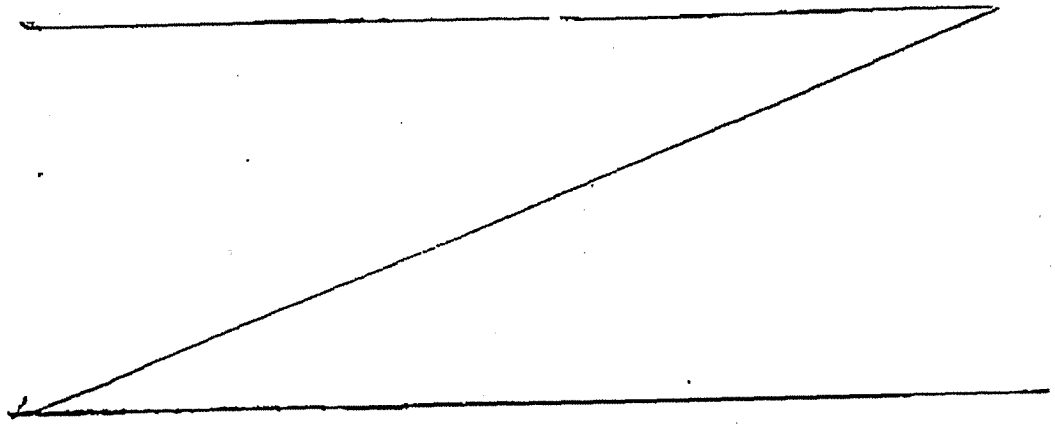
According to the manufacturing of the femoral and tibial component of the endoprosthesis therefore the virtual image of such a template is used directly as well for the later tridimensional manufacturing of an corresponding implantation aid for the single components of the endoprosthesis. The severing planes taken over for the template are represented in the implantation aid as guiding slots for an oscillating sawing blade, by which in the later surgical intervention a separation that means segmentation of the damaged joint parts in the joint bones is performed. When preparing the virtual image of the template therefore it also correspondently has to be considered carefully, that the later implantation aid may obtain in the damage knee such an exact positioning, so the sawing blade oriented for the resection of the damaged joint parts in the guiding slots achieves severing planes in the joint bone, which are exactly congruent with the fitting plane of the femoral and tibial components of the endoprosthesis which were defined by the marked severing planes of their visual pattern. Such templates and their implantation aids respectively are therefore to be designed in the form of caps to obtain an enveloping of the severing planes which therefore present themselves in the template as a negative image of the later resection plane of the joint bone which are obtained by means of the implantation aid in the later knee joint surgical intervention.

[0012] The visual patterns for the femoral and tibia components of an endoprosthesis and for the femoral and tibial components of a corresponding implantation aid are then processed for the manufacturing of congruent three-dimensional parts. For the processing the so-called "Rapid Prototyping" is available by which so-called STL patterns are obtained which may be used for the preparation as patterns for the production of mouldings in a casting process. For the tibial component of the endoprosthesis hereby a metallic and a plastic part which are meant to achieve a central positioning between the metallic part of the tibial component and the also as a metallic component performed femoral component of endoprosthesis can be provided to be arranged in the joint bone. For the manufacturing of the implantation aid as well the visual pattern of the template are processed by the "Rapid Prototyping" to provide corresponding STL patterns, which are made, e.g., of epoxy resin and are further provided with those guiding slots corresponding to the pattern given by the overtaken marked severing planes.

)

[0013] For the performance of the knee joint surgical intervention for the attending physician therefore will be disposable an operative set oriented on the damaged knee joint consisting in femoral and tibial components of an endoprosthesis and femoral and tibial components of an corresponding implantation aid manufactured through the procedure of the invention described before. After opening the knee joint, first in the tibia and subsequently in the femur the damaged joint parts are separated that means segmented using therefore the implantation aid to guide an oscillating sawing blade. So in the joint bone severing planes are obtained which snugly are congruent with the femoral and tibial components of the endoprosthesis which then by taking advantage of the anchoring means may be anchored in the severing plane in a cementless procedure. In case of absence of special anchoring means the components of the endoprosthesis may be glued directly with the severing planes or alternatively as well a so-called cemented procedure will find application to achieve an physiological perfect fitting for the components of the endoprosthesis before the subsequent closing that means sewing of the knee joint.

[0014] The preparation of the endoprosthesis may include the preparation of a component which will be used for the patella of the damaged knee joint. The method could further be also applied for the performance of surgical interventions in other joints for example of the ankle joint, or of finger and toe joints, and it could also be used for all reconstructions of bone and cartilage tissue as well as soft tissues.



PATENT CLAIMS

1. Method of producing an endoprosthesis as articular substitute for knee joints in the realisation of surgery on the knee joint, comprising the following steps:

   (a) production of a tomographic image of the damaged knee joint;

   (b) virtual correction of the tomographic image for approximating the contours of at least the femoral and tibial articular parts of the damaged knee joint to their contours in an unaffected knee joint;

   (c) virtual separation of the corrected articular femoral and tibial parts as image models for the endoprosthesis, with the separation being carried out at marked cut surfaces that are specified for the detachment of damaged joint parts on the articular bones by the time of the subsequent surgical operation;

   (d) transfer of the cut surfaces marked for the virtual detachment of the corrected femoral and tibial joint parts for producing a virtual image of a model, separately for the femur and the tibia of the damaged knee joint as image model of an implantation-assisting material congruent with precise fit with the damaged knee joint, wherein the transferred cut surfaces are realised in the form of guiding slots that guide an oscillating saw blade in the subse-

quent surgical operation for the detachment carried out on the articular bones of the damaged joint parts;

(e) production of the femoral and tibial components of the endoprosthesis and of three-dimensional femoral and tibial components of the corresponding implantation-assisting material on the basis of their image model.

2. Method according to Claim 1, wherein the corrected femoral and tibial articular parts are completed in terms of image at the marked cut surfaces by precisely fitting anchorage-assisting means for the subsequent three-dimensional components of the endoprosthesis at the resection surfaces on the articular bones.

3. Method according to Claim 1 or 2, wherein the tomographic images are produces by computer tomography or nuclear magnetic resonance tomography.

4. Method according to any of the Claims 1 to 3, wherein the virtual correction of the tomographic image of the damaged knee joint is carried out by hand or by means of the image of a mirror-image picture of an unaffected knee joint of the patient, that is opposite to the damaged knee joint.

5. Method according to any of the Claims 1 to 3, wherein the virtual correction of the tomographic image of the damaged knee joint is carried out by a comparison against the images of unaffected knee joints, which present articular surfaces at least of the femur and the tibia, which are comparable to the damaged knee joint.

6. Surgical operation set for carrying out surgery on knee joints, comprising:

(c1) femoral and tibial components of an endoprosthesis, which are derived from image models created by tomography of articular femoral and tibial parts that have been virtually detached at marked cut surfaces of an image of a damaged knee joint, which was created by tomography and corrected, and

(d1) femoral and tibial components of a three-dimensional implantation-assisting material, which are derived from image models of a model oriented towards the cut surfaces of the corrected image of the damaged knee joint, sepa-

rately for the femur and the tibia, with the cut surfaces on the two femoral and tibial components of the implantation-assisting material being realised in the form of guiding slots for guiding an oscillating saw blade.

7. Surgical operation set according to Claim 6, wherein the femoral and tibial components of the endoprosthesis are provided with spigot-shaped projections for fitting into bores drilled into the resection surfaces of the articular bones on the damaged knee joint.

8. Surgical operation set according to Claim 6 or 7, wherein the tibial component of the endoprosthesis is composed of a synthetic part and a metal part, with the synthetic part presenting a central arrangement between the metal part of the tibial component and the femoral part of the endoprosthesis, which is equally configured in the form of a metal part.